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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,665	10/11/2005	Martin G. Reese	OM1100-2	2598

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

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10/13/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,665	REESE ET AL.	
	Examiner	Art Unit	
	Carolyn Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *2-3,13-14,17,20,22-23,26-30,32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-12,15,16,18,19,21,24,25 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 8/2/10, are acknowledged. Amended claims 1, 8, 9 and new claims 27-32 are acknowledged. Claims 22-23 and 26 remain withdrawn from consideration due to being drawn to non-elected Groups. Claims 2, 3, 13, 14, 17, 20, 27-30, and 32 are withdrawn from consideration due to being drawn to non-elected species.

Applicant's arguments, filed 8/2/10, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant inquired as to the status of the title correction request, filed 6/19/2009. The title has been updated/corrected in the USPTO records.

Claims herein under examination are 1, 4-12, 15-16, 18-19, 21, 24, 25, and 31.

Claim Rejections - 35 USC § 112, First paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER

Claims 1, 4-12, 15-16, 18-19, 21, 24-25, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues written support for claim amendments are provided on pages 10, 13, 14, and originally filed claims. There does not appear to be adequate written support for "indirectly linked with a phenotypic attribute" (instant claims 1 and 9). While there is written support for "degree of linkage" (claim 26) and "causally linked with breast cancer" (0023), there does not appear to be adequate written support for "indirectly linked with a phenotypic attribute" which differs in scope.

Because there does not appear to be adequate written support for "indirectly linked with a phenotypic attribute" (instant claims 1 and 9) in the specification, claims, and/or drawings, as originally filed, this limitation is considered to be NEW MATTER. Claims 4-8, 10-12, 15-16, 18-19, 24-25, and 31 are also rejected due to their dependency from claims 1 and 9. This rejection is maintained and reiterated for reasons of record for claims 1, 4-12, 15-16, 18-19, 21, 24-25 and necessitated by amendment for claim 31.

Applicant argues that pages 10, 13, and 14 provide adequate written support for "indirectly linked with a phenotypic attribute" (instant claims 1 and 9) and specifically mentions "the preselection of the set of markers is based on genotype/phenotype associations with disease conditions or predispositions for disease conditions". This statement is found unpersuasive as associations with disease conditions or predispositions for disease conditions are not commensurate in scope with "indirect" linkage.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-12, 15-16, 18-19, 21, 24, 25, and 31 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Blumenfeld et al. (US 6,528,260 B1). This rejection is maintained and reiterated for reasons of record for claims 1, 4-12, 15-16, 18-19, 21, 24, 25 and necessitated by amendment for claim 31.

Blumenfeld et al. disclose a method for determining the probability of exhibiting a phenotypic attribute (col. 9, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs; col. 84, first paragraph to col. 86, first paragraph), as stated in the preamble of instant claim 1 as well as the determining step of instant claim 9. Blumenfeld et al. disclose evaluating genomic markers for zygosity from a preselected set of markers wherein the markers are preselected based on association studies to be linked with a phenotypic attribute (col. 10, fourth paragraph; col. 13, last paragraph to col. 14, first paragraph; col. 16, last paragraph to col. 17, first paragraph; col. 67, third paragraph; col. 73, second paragraph; col. 74, second paragraph; col. 84, second paragraph), comparing zygosity of preselected markers to a

multivariate scoring matrix to obtain a matrix score that correlates patterns (col. 14, last paragraph; col. 31, 32, 33, and col. 83, second paragraph) as well as determining the probability of exhibiting a phenotypic attribute based on the marker score (col. 84, second paragraph to col. 86, first paragraph; col. 91, second paragraph) using software on a computer (col. 87, second paragraph; col. 97, second paragraph to col. 98, last paragraph), as stated in instant claims 1, 9. Blumenfeld et al. disclose using promoter sequences (col. 10, last paragraph; col. 31, first paragraph; col. 64, fifth paragraph), as stated in instant claims 4 and 5. Blumenfeld disclose selecting markers prioritized by degree of phenotypic significance and markers that map at least about 1000 discrete loci (col. 39, last paragraph to col. 40, first paragraph; col. 79, third paragraph; col. 89, line 47 to col. 90, first paragraph), as stated in instant claim 7. Blumenfeld et al. disclose performing analysis when some information concerning the biology of the trait is available (col. 21, second paragraph) and selecting markers from some of the Tables (i.e. 11A-B; col. 12, third paragraph; col. 17, first three paragraphs; col. 25, second paragraph) which represents scoring matrix prioritizing markers with respect to criteria of quality of supporting research, as stated in instant claims 1, 8, 9, 31. Blumenfeld et al. disclose assessing individual risk (col. 9, first paragraph), screening markers with higher probabilities (col. 65, lines 53-55; col. 87, lines 60-67), identifying genotypic characteristics of an individual that correlate with phenotypic characteristics (claim 1 col. 9, first paragraph; col. 10, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs), displaying output to a user (col. 98, last paragraph) and accessing information on the computer (col. 97, last paragraph), as stated in instant claim 9. Blumenfeld et al. disclose genotyping individuals for a DME-related biallelic marker that is selected individually or in combination with other markers (col. 13, last paragraph), detecting an

association between an allele and a phenotype (col. 14, second paragraph), reiterating experiments at least 100 times (col. 90, fourth paragraph), looking at various phenotypic trait selection criteria, such as clinical phenotype, age, family history, and severity (col. 84, second paragraph) as well as other criteria such as drug treatment responses, including drug treatments having different degrees of response or side effects (col. 84, last two paragraphs), determining probabilities of phenotypes (col. 84, second paragraph), formatting tables of information, and outputting to a user (i.e. col. 98, last paragraph; col. 103, last paragraph; Tables 10, 11A-B, 21, 22, 23), analysis regarding probability that person with a given genotype will exhibit a trait (col. 9, fourth paragraph), as stated in instant claims 9, 10, 15, 16, (and i.e. see Tables above, inherently prior to communication to individual, the identity of individual is not associated with data, as stated in instant claim 21). Blumenfeld et al. disclose studying physiological consequences at the cellular and organism level (col. 45, last paragraph to col. 46, first paragraph), various databases with information on sequence variations and how genotypes affect common diseases, drug responses, and other complex phenotypes (col. 111, first and third paragraphs), and user-specified thresholds of significance (col. 32, first paragraph) as stated in instant claims 11 and 12. Blumenfeld et al. disclose taking into account effects of subpopulations with discriminatory potential or considering close familial relationships (col. 110, second paragraph) which represents an organizational matrix that groups phenotypic characteristics related to similar physiological systems together, as stated in instant claim 18. Blumenfeld et al. disclose assessing risk to better target therapeutic strategies defining individual drug usage based on benefit/risk prognosis as well as efficacy/tolerance prognosis (col. 9, first paragraph) and scoring the results of determination of the identity of a nucleotide at a marker

with respect to the test subject's risk of contracting disease, drug response, or chances of suffering side effects (col. 41, second paragraph) which represents ranking phenotypic characteristics as a function of potential impact on the individual's lifestyle, as stated in instant claim 19. Blumenfeld et al. disclose characteristics of genomic ethnicity of an individual (col. 64, last paragraph; col. 95, fifth paragraph). Blumenfeld et al. disclose diseases including disorders of male infertility (col. 27, first paragraph) and studies among affected relatives by analysis of two individuals, including sib pair analysis (col. 80, second paragraph). Blumenfeld et al. disclose population-based association studies (col. 83, last paragraph) and inclusion criteria for selection as well as linkage studies and statistical analysis (col. 83, second to last paragraph to col. 85, last paragraph), and pharmacogenomic analysis (col. 1, second paragraph), as stated in instant claims 24 and 25.

Thus, Blumenfeld et al. anticipate the instant invention.

Applicant summarizes Blumenfeld et al. and the instant invention. Applicant argues that Blumenfeld et al. disclose association studies linking a previously non-identified marker to a phenotypic attribute while the present invention is not based on identification of genetic markers per se. This statement is found unpersuasive as Blumenfeld et al. disclose the claimed method as it is broadly and reasonably interpreted. For instance, the limitation "markers are preselected based on association or other studies to be directly or indirectly linked with a phenotypic attribute" can be interpreted broadly and reasonably to be any markers that happen to be preselected, "based on" terminology is very broad encompassing just about any involvement with "association or other studies" (i.e. any study), "directly or indirectly linked" can be broadly

and reasonably interpreted to be any study in some way involved with a phenotypic attribute. Such broad language is anticipated by Blumenfeld et al. who disclose a method for determining the probability of exhibiting a phenotypic attribute (col. 9, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs; col. 84, first paragraph to col. 86, first paragraph). In addition, Blumenfeld et al. disclose evaluating genomic markers for zygosity from a preselected set of markers wherein the markers are preselected based on association studies to be linked with a phenotypic attribute (col. 10, fourth paragraph; col. 13, last paragraph to col. 14, first paragraph; col. 16, last paragraph to col. 17, first paragraph; col. 67, third paragraph; col. 73, second paragraph; col. 74, second paragraph; col. 84, second paragraph). Applicant argues that Blumenfeld et al. describe conducting an association study, linking to a known phenotype or trait with a marker that is not pre-selected for that particular phenotype. This statement is found unpersuasive as the instant claim 1 can be reasonably interpreted in a broader manner than what is argued, as discussed above. Blumenfeld et al. disclose estimating the frequency of an allele (col. 13, last paragraph) which represents a marker that has been preselected. Blumenfeld et al. disclose a list of markers in Table 11A which represents preselection (col. 13, last paragraph). Blumenfeld et al. disclose genotyping to detect alleles of markers known to be associated with a given trait (col. 67, third paragraph) which represents preselected markers. Applicant argues the Blumenfeld et al. markers cannot be pre-selected for the purpose of determining probability of exhibiting a particular trait because the marker is not previously identified. This statement is found unpersuasive as Blumenfeld et al. disclose genotyping to detect alleles of markers known to be associated with a given trait (col. 67, third paragraph) which represents preselected markers. Applicant argues that there is no disclosure regarding a multivariate scoring matrix.

This statement is found unpersuasive as Blumenfeld et al. disclose comparing zygosity of preselected markers to a multivariate scoring matrix to obtain a matrix score that correlates patterns (col. 14, last paragraph; col. 31, 32, 33, and col. 83, second paragraph) as well as determining the probability of exhibiting a phenotypic attribute based on the marker score (col. 84, second paragraph to col. 86, first paragraph; col. 91, second paragraph). Applicant summarizes Blumenfeld et al. and argues the instant invention does not require or envision the identification of new markers, because the markers are known and pre-selected for the probability study. This statement is found unpersuasive as the instant claims do not preclude identification of markers, the instant claims do not recite markers are known, and the preselected markers have been interpreted broadly and reasonably as discussed above. Applicant argues Blumenfeld et al. do not disclose the limitations of instant claim 9. This statement is found unpersuasive because Blumenfeld et al. disclose these limitations, as follows:

Blumenfeld et al. disclose a method for determining the probability of exhibiting a phenotypic attribute (col. 9, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs; col. 84, first paragraph to col. 86, first paragraph), as stated in the preamble of instant claim 1 as well as the determining step of instant claim 9. Blumenfeld et al. disclose evaluating genomic markers for zygosity from a preselected set of markers wherein the markers are preselected based on association studies to be linked with a phenotypic attribute (col. 10, fourth paragraph; col. 13, last paragraph to col. 14, first paragraph; col. 16, last paragraph to col. 17, first paragraph; col. 67, third paragraph; col. 73, second paragraph; col. 74, second paragraph; col. 84, second paragraph), comparing zygosity of preselected markers to a multivariate scoring matrix to obtain a matrix score that correlates patterns (col. 14, last

paragraph; col. 31, 32, 33, and col. 83, second paragraph) as well as determining the probability of exhibiting a phenotypic attribute based on the marker score (col. 84, second paragraph to col. 86, first paragraph; col. 91, second paragraph) using software on a computer (col. 87, second paragraph; col. 97, second paragraph to col. 98, last paragraph), as stated in instant claims 1, 9. Blumenfeld et al. disclose assessing individual risk (col. 9, first paragraph), screening markers with higher probabilities (col. 65, lines 53-55; col. 87, lines 60-67), identifying genotypic characteristics of an individual that correlate with phenotypic characteristics (claim 1 col. 9, first paragraph; col. 10, fourth paragraph; col. 67, third paragraph; col. 80, last two paragraphs), displaying output to a user (col. 98, last paragraph) and accessing information on the computer (col. 97, last paragraph), as stated in instant claim 9. Blumenfeld et al. disclose genotyping individuals for a DME-related biallelic marker that is selected individually or in combination with other markers (col. 13, last paragraph), detecting an association between an allele and a phenotype (col. 14, second paragraph), reiterating experiments at least 100 times (col. 90, fourth paragraph), looking at various phenotypic trait selection criteria, such as clinical phenotype, age, family history, and severity (col. 84, second paragraph) as well as other criteria such as drug treatment responses, including drug treatments having different degrees of response or side effects (col. 84, last two paragraphs), determining probabilities of phenotypes (col. 84, second paragraph), formatting tables of information, and outputting to a user (i.e. col. 98, last paragraph; col. 103, last paragraph; Tables 10, 11A-B, 21, 22, 23), analysis regarding probability that person with a given genotype will exhibit a trait (col. 9, fourth paragraph), as stated in instant claim 9. Applicant's arguments are deemed unpersuasive for the reasons given above.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. If you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, please call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

October 7, 2010

/Carolyn Smith/
Primary Examiner
AU 1631